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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,332	06/27/2001	Joseph Solus	0942.4250003	4572

26111 7590 02/26/2003

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/891,332

Applicant(s)
Solus et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 21, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-33, 66, and 69-72 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 9-15, 21-29, and 66 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 16-20, 30-33, and 69-72 is/are objected to.
- 8) ☒ Claims 1, 2, 5-33, 66, and 69-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. The amendment filed 11/21/2002 has been entered.
2. The rejection of claims 7-8, 21-22 and 66 under 35 U.S.C. 112, second paragraph is withdrawn.
3. The rejection of claims 1-2, 5 and 66 under 35 U.S.C. 102(b) as being anticipated by Mullis et al. (4,965,188) is withdrawn.
4. The rejection of claims 1-2, 5-19 and 23-33 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hughes et al. (6,015,668) is withdrawn.
5. The rejection of claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (6,015,668) as applied to claims 1-2, 5-19 and 23-33 above, and further in view of Huo (5,922,535) is withdrawn.

NEW GROUNDS REJECTION

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-2, 5-6, 9-15, 23-29 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caetano-Anolles et al. (WO 95/33853).

Caetano-Anolles et al. disclose a method of DNA fingerprinting in which a Stoffel fragment of a DNA polymerase from *Thermos aquaticus* is applied to the reaction. The fragment of the DNA polymerase is a highly thermostable, recombinant DNA polymerase and no associated 3'-5' or 5'-3' exonuclease activity (See pg. 25, third paragraph).

Caetano-Anolles et al. do not disclose that the DNA polymerase with no associated 3'-5' or 5'-3' exonuclease activity to reduce in ability to add one or more non-template nucleotide to the 3' terminus of a DNA molecule.

Based upon the definition of "said DNA polymerases" which are mutated to be substantially reduced in the ability to add one or more non-templated nucleotides to the 3' terminus of a DNA molecule in the specification and do not have 3' exonuclease activity (See pg. 25, lines 9-15).

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One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the DNA polymerase of Caetano-Anolles et al. to the method of identifying, analyzing or typing a polymorphic DNA fragment in a DNA sample, because the polymerase gave improved performance in DAF reactions and particularly is more efficient in amplification of short products and able to produce more informative fingerprints than other DNA polymerases (See pg. 25, third paragraph). Further, one of ordinary skill in the art would have also made the kit containing the polymerase of Caetano-Anolles et al. because constructing a kit including the components used for performing a method was well known routine practice in the art for convenience. It would have been prima facie obvious to carry out the method and construct the kit as claimed.

8. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caetano-Anolles et al. (WO 95/33853) as applied to claims 1-2, 5-6, 9-15, 23-29 and 66 above, and further in view of Huo (5,922,535).

The teachings of Caetano-Anolles et al. are set forth in section 7 above.

Caetano-Anolles et al. do not disclose determining the relationship between a first individual and a second individual in which the first individual is known and the second individual is unknown a method of identifying sequence differences between or among nucleic acid population via polymerase chain reaction (See the Abstract and column 1, lines 52-54).

Huo also addresses that in the conventional way, normal sequence is already known (See column 1, lines 13-20).

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One of ordinary skill in the art at time of the invention would have been motivated to combine the teachings of the DNA polymerase of Caetano-Anolles et al. and the teachings of Huo to make the instant invention that the relationship between two individuals is determined via polymerase chain reaction. The motivation is that the DNA polymerase of Caetano-Anolles et al. gave improved performance in DAF reactions and particularly is more efficient in amplification of short products and able to produce more informative fingerprints than other DNA polymerases (See pg. 25, third paragraph) and the teachings of Huo provide the method for the detection of sequence differences between two or more nucleic acid populations. Thus, it would have prima facie obvious to carry out the method involving that the relationship between two individuals is determined via polymerase chain reaction as claimed.

Allowable Subject Matter

9. Claims 7-8, 16-20, 30-33, 69-72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

No prior art has been found teaching or suggesting a polymerase which comprises mutations in the O-helix of the polymerase or the modification at position R(Arg) or F(Phe) or

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K(Lys) of the O-helix that reduce, substantially reduce or eliminate the ability of the polymerase to add non-templated 3' nucleotides to a synthesized nucleic acid molecule.

Summary

11. No claims are allowable.
12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

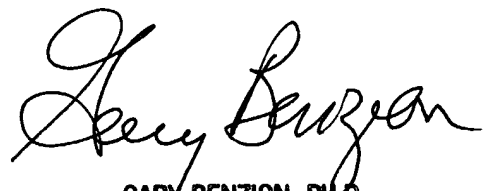
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T.
February 21, 2003



GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600